



September 18, 2009

Dear Healthcare Professional:

I am writing to inform you that, in consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare is voluntarily initiating a recall of certain lots of Children's and Infants' TYLENOL® products that were manufactured between April 2008 and June 2008. The full list of recalled product lots is below.

The company has implemented this recall because examination of bulk raw material detected that one of the inactive ingredients did not meet internal testing requirements. Specifically, the gram-negative bacteria *Burkholderia cepacia* (*B. cepacia*) was detected. The portion of raw material in which the bacteria was found was isolated and was not used in the production of any finished product. However, it was decided, as a precaution, to recall all product that utilized any of the raw material manufactured at the same time as the raw material that tested positive for the bacteria. Please note: No bacteria has been detected in finished product and the finished product has met all specifications.

A review of the relevant published scientific literature regarding *B. cepacia* indicates that while ingestion of contaminated pharmaceutical product is not known to be a route of transmission of *B. cepacia* infection, infection has been reported following the use of contaminated pharmaceutical products such as mouthwashes and nasal sprays. Adverse health consequence of *B. cepacia* infections could be potentially severe especially in high-risk patients, such as those with underlying pulmonary disease, cystic fibrosis or compromised immune systems.

McNeil has conducted an assessment of post-marketing safety surveillance data and did not identify any safety signals or batch-related safety concerns for Infants' and Children's TYLENOL® products over the time period, starting with the introduction of these batches, in or around April 2008.

McNeil is advising parents and caregivers who have administered affected product to their child or infant and have concerns to contact their healthcare providers. Parents and caregivers can find the lot numbers on the bottom of the box containing the product and also on the sticker that surrounds the product bottle. If your patients determine that they have affected product, they can contact our Customer Care Center at 1-800-962-5357 and we will send them a coupon for a new bottle.

If you have any questions, please call our Medical Affairs Department at 1-800-962-5357 (available Monday-Friday 8 a.m. to 8 p.m. Eastern Time).

Sincerely,

Edwin K. Kuffner, MD
Vice President, Medical Affairs
McNeil Consumer Healthcare

Recalled Products - Full List

UPC #	Code #	Lot #	Product Description
300450391049	3910400	SBM041, SBM067, SCM037, SDM027, SEM109	Children's TYLENOL® Plus Cold MS Suspension 4 oz. Grape
300450296047	2960400	SBM042, SCM015, SCM036, SDM034	Children's TYLENOL® Suspension 4oz. Grape
300450407047	4070400	SBM043, SBM044, SCM029	Children's TYLENOL® Suspension 4oz.

			Bubble Gum
300450493040	4930400	SBM045, SCM011, SCM030, SDM035	Children's TYLENOL® Suspension 4oz. Strawberry
300450122407	1224000	SBM064, SCM033, SDM020	Infants' TYLENOL® Grape Suspension Drops 1/4oz.
300450186157	1861500	SBM065, SCM005, SCM006, SDM032	Infants' TYLENOL® Suspension 1/2oz. Cherry
300450166043	1660400	SBM066, SCM068	Children's TYLENOL® Dye Free Suspension 4oz. Cherry
300450123046	1230400	SBM068, SCM035, SCM070, SCM080, SDM005	Children's TYLENOL® Suspension 4oz. Cherry
300450249043	2490400	SBM069, SBM070, SCM081, SDM006	Children's TYLENOL® Plus Cough & Runny Nose 4oz. Cherry
300450122155	1221500	SCM012, SCM067, SDM007, SDM068	Infants' TYLENOL® Suspension Drops 1/2oz. Grape
300450386045	3860400	SCM013, SCM014, SCM069	Children's TYLENOL® Plus Flu 4oz. Bubble Gum
300450387042	3870400	SCM016, SFM024	Children's TYLENOL® Plus Cold Suspension 4oz. Grape
300450247049	2470400	SCM017	Children's TYLENOL® Plus Cough/ST Suspension 4oz. Cherry
300450122018	1220100	SCM082, SDM039, SDM040	Infants' TYLENOL® Suspension Drops 1oz. Grape
300450167019	1670100	SCM083, SCM084, SDM008	Infants' TYLENOL® Dye Free Suspension 1oz. Cherry
300450123015	1230100	SDM064	Children's TYLENOL® Pediatric Suspension 1oz. Cherry
300450186300	1863000	SDM038, SDM009	Infants' TYLENOL® Suspension Drops 1oz. Cherry
300450390042	3900400	SDM033	Children's TYLENOL® Plus Cold/Allergy 4oz. Bubble Gum
300450122100	1221000	SDM078	Infants' TYLENOL® Drops 1oz. Grape
350580144183	1221800	SCM034	Infants' TYLENOL® Grape Suspension Drops H/G 1/2oz.
350580123034	1230300	SDM028	Children's TYLENOL® Suspension 4oz. Cherry, Hospital Govt.